510(k) Summary
for the
E.M.S. Electro Medical Systems SA
SWISS LITHOBREAKER

JAN 16 2013

1. SUBMITTER/510(K) HOLDER

E.M.S. Electro Medical Systems SA
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Date Prepared: September 27, 2012

2. DEVICE NAME

Proprietary Name: SWISS LITHOBREAKER
Common/Usual Name: Endoscopic intracorporeal lithotripsy
Classification Name: Electrohydraulic lithotripsy

3. PREDICATE DEVICES

The proposed SWISS LITHOBREAKER is substantially equivalent to the following legally marketed medical devices:

- E.M.S. Electro Medical Systems S.A., Swiss LithoClast Master (aka Swiss LithoClast Ultra) (K012445)
- The Laryngial Mask Company Limited, LMA StoneBreaker (K062475)

The probes used by the SWISS LITHOBREAKER were previously cleared by FDA in K012445, and K973788. The LithoVac lv3 suction system was previously cleared in K012445. The sterile drape was previously cleared in K110724.

4. DEVICE DESCRIPTION

The EMS SWISS LITHOBREAKER is a handheld, standalone, battery operated intracorporeal lithotripter which uses a mechanical impact drive to fragment urinary tract calculi in the kidney, ureter, and bladder. The device generates around 3 impacts in continuous mode per second which are transmitted through the probes on

the stones or a lower frequency by "single-pulse" mode, depending on the activation time of the button. The probes are introduced into the working channels of suitable endoscopes. The energy is sustained and stable throughout the life of the battery and the frequency drops only at the end of the battery life. An optional suction handpiece allows extraction of fragmented stones.

The proposed device consists of the following:

- Handpiece including powerpack
- LithoClast probes, non-sterile reusable and sterile single use
- LithoVac lv3 suction system with suction tubes

The SWISS LITHOBREAKER is also supplied with accessories for cleaning (endcap), periodic maintenance (O-rings), probe accessories (interface and probe guide), AAA batteries and sterile drapes.

5. INTENDED USE

The SWISS LITHOBREAKER is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

6. PRINCIPLES OF OPERATION

The proposed SWISS LITHOBREAKER can be used as a lithotripter only or in combination with a suction device LithoVac lv3. The probes mounted on the handpiece transmit impact generated waves of sufficient strength to fragment urinary tract calculi of any composition. LithoVac lv3 suction system can be combined with the lithotripsy device to provide simultaneous suction to remove calculi fragments.

The SWISS LITHOBREAKER handpiece is a battery operated lithotripter which uses a mechanical impact drive to fragment urinary tract calculi in the kidney, ureter, and bladder. The device works at an impact frequency of approximately 3Hz in either a continuous mode or "single-pulse" mode, depending on the time the activation button is depressed and probes are used through the working channels of suitable endoscopes.

Probes are mounted on the handpiece and the probes are inserted into the working channel of an endoscope. The LithoVac lv3 suction system may be used in conjunction with the SWISS LITHOBREAKER handpiece and probe to allow for suctioning during procedures. The probe is brought into contact with the calculi, and the LithoBreaker is activated.

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The proposed SWISS LITHOBREAKER is substantially equivalent to the previously cleared Swiss LithoClast Master (K012445) and the handheld LMA StoneBreaker (K062475).

Differences between the proposed SWISS LITHOBREAKER and the predicate Swiss LithoClast Master (K012445) and the handheld LMA StoneBreaker (K062475) are limited to the power sources used and the mechanism used to translate the power into impacts which are transmitted through the probes, resulting in non-significant variations in performance. The design and function of the lithotripsy probes of the proposed SWISS LITHOBREAKER are identical to the EMS LithoClast probes.

Testing demonstrated that the SWISS LITHOBREAKER fulfills the prospectively defined performance specifications. The similarities in intended use, operational characteristics, and technological characteristics between the proposed SWISS LITHOBREAKER and the predicate Swiss LithoClast Master (K012445) and LMA StoneBreaker (K062475) lead to a conclusion of substantial equivalence between the proposed and predicate devices. A side-by-side comparison of the predicate devices and the proposed device is provided in Table 5-1 at the end of this section.

8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Testing was performed to verify compliance of the SWISS LITHOBREAKER with the following standards:

- ANSI/AAMI ST79:2006, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities"
- ISO 17664 (2004), "Sterilization of Medical Devices – Information to be provided by the Manufacturer for the Processing of Resterilizable Medical Devices"
- ANSI/AAMI/ISO 17665-1:2006 "Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices"
- IEC 60601-1:1988 +A1: 1991 + A2: 1995, "Medical electrical equipment, Part1: General requirements for safety"
- IEC 60601-1-2, "Medical electrical equipment. Part 1 General requirements for safety – Part 2 Collateral standard: Electromagnetic compatibility: Requirements and Tests" (2007).

- ISTA 2A (2008), "ISTA Preshipment Testing Procedures- Combination Tests for Packaged-Products 150 lb (68 kg) or Less"

The results of this testing confirm that the SWISS LITHOBREAKER is safe and effective for the intended use described in Section 5.

In addition, the SWISS LITHOBREAKER was tested as compared to the predicates with respect to the following:

- Probe Tip Displacement
- Probe Tip Velocity
- Stone Breakage/Clearance
- Stone Displacement (Retropulsion)
- Energy Output

The results of this testing confirm that the SWISS LITHOBREAKER is substantially equivalent to the predicates.

9. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was conducted for this submission.

10. Summary of Other Information

No other information is available.

11. Conclusions Drawn from Non-Clinical and Clinical Tests

Based on the information and supporting documentation provided in the premarket notification, the SWISS LITHOBREAKER is substantially equivalent to the cited predicate devices. Testing demonstrates that the SWISS LITHOBREAKER fulfills prospectively defined design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2013

EMS Electro Medical Systems SA
% Ms. Suzanne Goodman, BSE, RAC
Regulatory Project Manager, Medical Devices
Aptiv Solutions
225 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K123038
Trade/Device Name: SWISS LITHOBREAKER
Regulation Number: 21 CFR § 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: Class II
Product Code: FFK
Dated: November 30, 2012
Received: December 6, 2012

Dear Ms. Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123038

Device Name: SWISS LITHOBREAKER

Indications for Use:

The SWISS LITHOBREAKER is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123038